Institutional Review Board

North Dakota Department of Human Services

On-site Adverse Event Report

- **Any adverse events that occur during the study must be reported directly to the DHS Risk Manager (701-328-2311).**

Principal investigator: _____
Dept: _____
Phone: _____
Campus address: _____
Protocol title: _____

DESCRIPTION OF THE ADVERSE EVENT

1. Is this an initial report or follow-up report? _____
2. When did the adverse event begin? _____
3. When did you learn of the event? _____
4. Describe the adverse event in one sentence:

_____

_____

RESEARCH SUBJECT INFORMATION

1. Subject's age: _____
2. Subject's gender: _____
3. Subject's ID #: _____
4. The subject's participation will be: (Circle)
    a. Continued
    b. Discontinued
    c. Delayed
    d. N/A (explain)

_____

_____

_____

_____

Proposal #_____

EVENT INFORMATION

1. Do you consider this adverse event related to the study? (Circle)
   a. Definitely related
   b. Probably related
   c. Possibly related
   d. Probably not related
   e. Definitely not related

2. Does this adverse event change the risk/benefit ratio? (Circle)
   a. No
   b. Yes (explain)

   _____
   _____
   _____

3. Is this adverse event already listed as a risk in the informed consent?
   a. No
   b. Yes (attach a copy of that page of the consent with the language highlighted)
   c. If you would like to add the event as a risk in the informed consent, submit two copies of the consent. One must have the revisions highlighted and one must be a clean copy.
   d. If you are not adding the event as a risk in the informed consent, explain why not.

   _____
   _____
   _____
   _____

4. Has this adverse event occurred before?
   a. No
   b. Yes (what is the percentage of the study population, domestic and foreign, this has occurred in?)

      _____
      _____

5. Does this adverse event involve the use of a blinded study?
   a. No
   b. Yes
   c. If Yes, was the blind broken?
      1. No
      2. Yes
   d. If the blind was broken, was the subject given the experimental drug, device or biologic?

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1. No
2. Yes

6. Does a Data Safety Monitoring Board (DSMB) oversee this study?
   a. No
   b. Yes

7. Provide any relevant history, comments and information:

_____
_____
_____
_____
_____
_____
_____
_____

COMPLIANCE

1. Did you comply with the reporting policy?
   a. No (attach an explanation)
   b. Yes

Principal Investigator Statement of Assurance

"I understand that I cannot initiate any changes in my approved protocol before I have received approval and complied with all contingencies."

_____ _____
Signature of Principal Investigator Date

Please return this application and any attachments to:

West Central Human Service Center
Attn: DHS IRB Chair
1237 West Divide Ave, STE. 5
Bismarck, ND 58501-1208

Proposal #_____